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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,587	02/25/2002	Edward J. Gavin	016866-008200US	6008

20350 7590 04/10/2007	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP	LAU, TUNG S	
TWO EMBARCADERO CENTER		
EIGHTH FLOOR	ART UNIT	PAPER NUMBER
SAN FRANCISCO, CA 94111-3834	2863	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

PTOL-90A (Rev. 10/06)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>19 March 2007</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-40</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-40</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>02/25/2002</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-SB/08)
    Paper No(s)/Mail Date <u>03/19/2007</u>.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1.   A request for continued examination under 37 CFR 1.114, including the fee set

forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since

this application is eligible for continued examination under 37 CFR 1.114, and the

fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous

Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's

submission filed on 03/19/2007 has been entered.

Information Disclosure Statement

2.   The information disclosure statement filed 03/19/2007 fails to comply with the

provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the date of the

publication of the references is/are missing. It has been placed in the application

file, but the information referred to therein has not been considered as to the

merits (items AL, AP and AS). Applicant is advised that the date of any re-

submission of any item of information contained in this information disclosure

statement or the submission of any missing element(s) will be the date of

submission for purposes of determining compliance with the requirements based

on the time of filing the statement, including all certification requirements for

statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

Claim Rejections - 35 USC § 101

3.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 101 that

form the basis for the rejections under this section made in this Office action:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and
requirements of this title.

Claims 1-40 are rejected under 35 U.S.C. 101 because the claimed invention is

directed to non-statutory subject matter.

In claim 1, the method that analyzes mass spectra using a computer including

entering data forming classification model. In claim 35, a computer readable

medium including entering code derived from mass spectra, code for forming

classification model. These claims appear to merely describe mathematical

transformation and lack of concrete and tangible result. The practical application

of the claimed invention cannot be realized until the information determined is

conveyed to the user. For the result to be tangible it would need to output to a

user or stored for later use. Hence the claims are treated as nonstatutory

functional descriptive material (See MPEP § 2106 and OG Notices: 22

November 2005, Guidelines for Subject Matter Eligibility,

http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm

See MPEP 2106 IV B (1) (b).

For instance in claim 1, the method steps of entering data, forming classification

model are data manipulation. This fails to present a concrete, tangible useful

result. An example of a concrete, tangible useful result may include displaying,

storing for further use, generating a control signal etc. of the forming

classification model.

For instance in claim 35, a computer readable medium including code for forming

classification model. This fails to present a concrete, tangible useful result. An

example of a concrete, tangible useful result may include displaying, storing for

further use, generating a control signal etc. of the forming classification model.

The applicant should review the disclosure to determine what type of tangible

result is being carried out in this instant application and such limitation be

included in the claim. For further guidance see

http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm

Double Patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4.   Claims 1-34 and 39-40 are rejected under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1-100 of

U.S. Patent No. 6,675,104 (copending application 09999081). Although the

conflicting claims are not identical, they are not patentably distinct from each

other because the subject matter claimed in the instant application is fully

disclosed in the previous application.

Claim 1 (10/084,587)	Claim 1, 2 (U.S. Patent 6,675,104)
1. A method that analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio, and <u>is created using a laser desorption ionization process;</u> and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process.	1. A method that analyzes mass spectra using a digital computer, the method comprising: a) entering into the digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio; and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process, which is a classification and regression tree process. 2. The method of claim 1 wherein the mass spectra are selected from the group consisting of MALDI spectra, surface enhanced laser desorption/ionization

	spectra, and electrospray ionization spectra.

Claim Rejections - 35 USC § 102

5.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed
in the United States before the invention by the applicant for patent or (2) a patent granted on an application for
patent by another filed in the United States before the invention by the applicant for patent, except that an
international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this
subsection of an application filed in the United States only if the international application designated the United
States and was published under Article 21(2) of such treaty in the English language.

Claims 1-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Hitt et

al. (U.S. Patent application Publication 2003/0004402).

Regarding claim 1:

Hitt describes a method that analyzes mass spectra (page 3, section 0019) using

a digital computer (page 3, section 0023), the method comprising: a) entering

into a digital computer a data set obtained from mass spectra from a plurality of

samples (page 2, section 0016), wherein each sample is, or is to be assigned to

a class within a class set comprising two or more classes (page 3, section 0021),

each class characterized by a different biological status (page 2, section 0021),

and wherein each mass spectrum comprises data representing signal strength as

a function of time-of-flight (page 4, section 0032), mass-to-charge ratio, or a

value derived from time-of-flight or mass-to-charge ratio using laser ionization

desorption process (page 4, section 0032); and b) forming a classification model

which discriminates between the classes in the class set (page 4, section 0032),

wherein forming comprises analyzing the data set by executing code that

embodies a classification process comprising a recursive partitioning process

(page 4, section 0032).

Regarding claim 35:

Hitt describes a computer readable medium (page 3, section 0023) a) code for

entering data set obtained from mass spectra (page 3, section 0019) from a

plurality of samples (page 2, section 0016), wherein each sample is, or is to be

assigned to a class within a class set comprising two or more classes (page 3,

section 0021), each class characterized by a different biological status (page 3,

section 0021), and wherein each mass spectrum comprises data representing

signal strength as a function of time-of-flight (page 4, section 0032),

mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge

ratio using laser ionization desorption process (page 4, section 0032); and b)

forming a classification model which discriminates between the classes in the

class set (page 4, section 0032), wherein forming comprises analyzing the data

set by executing code that embodies a classification process comprising a

recursive partitioning process (page 4, section 0032).

Regarding claim 2, Hitt further describes the mass spectra are selected from the group consisting of MALDI spectra (page 4, section 0032), surface enhanced laser desorption/ionization spectra, and electrospray ionization spectra.

Regarding claim 3, Hitt further describes the class set consists of exactly two classes (page 1, section 0003)

Regarding claim 4, Hitt further describes samples comprise biomolecules selected from the group consisting of polypeptides and nucleic acids (page 3, section 0019).

Regarding claim 5, Hitt further describes the samples are derived from a eukaryote, a prokaryote or a virus (abstract).

Regarding claim 6, Hitt further describes a normal status (page 1, section 0007)and a pathological status (abstract).

Regarding claim 7, Hitt further describes un-diseased (page 1, section 0007), low grade cancer and high grade cancer (page, 1, section 0005).

Regarding claim 8, Hitt further describes comprise a drug-responder state and a drug-non-responder state (page 8, section 00077, medical condition of any state).

Regarding claim 9, Hitt further describes comprise a drug-responder state and a drug-non-responder state (page 8, section 00077, medical condition of any state).

.**Regarding claim 10,** Hitt further describes comprise a toxic state and a non-toxic state (page 8, section 00077, medical condition of any state).

Regarding claim 11, Hitt further describes exposure to drug (page 9, section

0082).

Regarding claim 12, Hitt further describes the data set is a known data set

(page 1, section 0008), and each sample is assigned to one of the classes before

the data set is entered into the digital computer (page 3, section 0017).

Regarding claim 13, Hitt further describes forming the classification model

comprises using pre-existing marker data to form the classification model (page

3, section 0024).

Regarding claim 14, Hitt further describes data representing signal strength as a

function of mass-to-charge ratio (page 1, section 0006); clustering the signals

having similar mass-to-charge ratios into signal clusters (page 1, section 0006);

selecting signal clusters having at least a predetermined number of signals with

signal intensities above a predetermined value (page 1, section 0006); identifying

the mass-to-charge ratios corresponding to the selected signal clusters (page 1,

section 0006); and forming the data set using signal intensities at the identified

mass-to-charge ratios (page 1, section 0006).

Regarding claim 15, Hitt further describes at least one of identifying features

that discriminate between the different biological statuses, and learning (page 3,

section 0018).

Regarding claims 16, 36, Hitt further describes neural network analysis (page 4,

section 0026).

Regarding claim 17, Hitt further describes interrogating the classification model to determine if one or more features discriminate between the different biological statuses (page 6, section 0059).

Regarding claim 18, Hitt further describes repeating and using a larger plurality of samples (page 7, section 0062).

Regarding claim 19, Hitt further describes cluster analysis (page 7, section 0064).

Regarding claim 20, Hitt further describes forming the data set, wherein forming the data set comprises obtaining raw data from the mass spectra (page 7, section 60) and then preprocessing the raw mass spectra data to form the data set (page 7, section 60).

Regarding claim 21, Hitt further describes the different classes are selected from exposure to a drug, exposure to one of a class of drugs and lack of exposure to a drug or one of a class of drugs (page 1, section 0005).

Regarding claim 21, Hitt further describes value derive from mass-charge-ratio (page 2, section 0016).

Regarding claim 22, Hitt further describes representing signal strength as a function mass-to-charge ratio or a value derived from mass-to-charge ratio (page 2, section 0016).

Regarding claims 23, 28, Hitt further describes entering data obtained from a mass spectrum of the unknown sample into a digital computer; and processing

the mass spectrum data using the classification model formed by the method

(page 2, section 0015).

Regarding claim 24, Hitt further describes comprise un-diseased, low grade

cancer and high grade cancer (page, 1, section 0005).

Regarding claim 25, Hitt further describes to a drug of one of a class of drugs

(page 8, section 00077, medical condition of any state).

Regarding claim 26, Hitt further describes response to a drug (page 8, section

00077, medical condition of any state).

Regarding claim 27, Hitt further describes toxicity status (page 8, section 00077,

medical condition of any state).

Regarding claims 29, 32, Hitt further describes code for entering data obtained

from a mass spectrum of an unknown sample into a digital computer; and code

for processing the mass spectrum data using the classification model formed

by the method to classify the unknown sample in a class characterized by a

biological status (page 2, section 0015).

Regarding claims 30, 33, 37, Hitt further describes a gas phase ion

spectrometer (page 1, section 0003); a digital computer adapted to process data

from the gas phase ion spectrometer; and the computer readable medium in

operative association with the digital computer (page 3, section 0023).

Regarding claims 31, 34, 38, Hitt further describes adapted to perform a laser

desorption ionization process (page 4, section 0032).

Regarding claims 39, Hitt further describes material is antibodies (page 6,
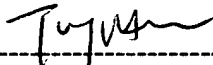
section 0059).

Regarding claims 40, Hitt further describes entering data obtained from a mass

spectrum of the unknown sample into a digital computer (page 3, section 0023),

wherein the mass spectrum is derived from a surface enhanced laser

desorption/ionization process (page 4, section 0032) using a substrate comprising

an affinity material, wherein the affinity material comprises antibodies (page 6,

section 0059); and processing the mass spectrum data using the classification

model formed by the method to classify the unknown sample in a class

characterized by a biological status (page 3, section 0021).

Response to Arguments

6.   Applicant's arguments filed 03/19/2007 have been fully considered and they are

not persuasive.

7.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Tung S Lau whose telephone number is 571-272-

2274. The examiner can normally be reached on M-F 9-5:30. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor,

John Barlow can be reached on 571-272-2269. The fax phone numbers for the

organization where this application or proceeding is assigned is 703-872-9306

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR

only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-

free).

Tung S. Lau
AU 2863, Patent examiner
April 3, 2007